

SUBJECT: [REDACTED] Abbreviated Risk Assessment for J15-27 to -30

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***** [REDACTED] *****

I. INTRODUCTION

The Agency has received a Microbial Commercial Activity Notice from DSM Bio-based Products and Services (DSM Nutritional Products) for four intergeneric strains of

[REDACTED]

[REDACTED]

II. TAXONOMY AND CHARACTERIZATION

A. Recipient Microorganism

[REDACTED]

B. Donor Microorganisms

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The other donor is *E. coli* which is a non-sporeforming Gram negative rod bacterium that is facultatively anaerobic with both a respiratory and fermentative type of metabolism. The typical habitat for *E. coli* is the lower intestines of humans and other warm-blooded animals.

III. PRODUCTION VOLUME

The anticipated production volumes for the modified active dry yeast were given by quarters as follows:

| [REDACTED] | [REDACTED] |
|------------|------------|
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |

[REDACTED]

IV. HISTORY OF USE

[REDACTED]

[REDACTED]

V. CONSTRUCT ANALYSIS

A. Construction of the Submission Microorganism

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

B. Potential Hazards of the Genetic Modifications

[REDACTED]

1. Introduced Genes

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

2. Potential for Horizontal Gene Transfer

[REDACTED]

[REDACTED]

VI. HUMAN HEALTH HAZARDS

The potential human health hazards associated with the four submission strains have been evaluated by Ward (2015).

[REDACTED]

[REDACTED]

[REDACTED]

VII. ECOLOGICAL HAZARDS

[REDACTED]

[REDACTED]

[REDACTED]

VIII. INTEGRATED RISK ASSESSMENT

[REDACTED]

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